3 August 2012
[18-12]

Approval Report – Application A1065

Packaging Size for Phytosterol-enriched Milk

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Lion Dairy and Drinks (formerly National Foods) to remove the current restriction on package size for milk enriched with phytosterols.

On 23 March 2012, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received ten submissions.

FSANZ approved the draft variation on 26 July 2012. The COAG Legislative and Governance Forum on Food Regulation[1] (Forum) was notified of FSANZ's decision on 2 August 2012.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

[1] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

Table of Contents

Supporting document

The following document which informed the assessment of this Application is available on the FSANZ website at
http://www.foodstandards.gov.au/foodstandards/applications/applicationa1065pack5285.cfm

SD1 Risk Assessment Report

1. Executive summary

This Application sought permission to remove the size restriction on packages of milk containing phytosterols, phytostanols and their esters (hereon after referred to as phytosterols). The packaging size or volume restriction was originally included as one part of a suite of risk mitigation measures aimed at encouraging appropriate use of phytosterol-enriched foods by target consumers and discouraging use by non-target consumers when phytosterols in milk was first approved in 2006.

Given the comprehensive nature of previous scientific evaluations, the primary focus of the assessment was to review aspects of the scientific evidence, and consider any new toxicological, clinical or epidemiological information on phytosterols that had become available over recent years, particularly since the most recent assessment by FSANZ in 2010. The assessment also considered any potential risk to public health and safety from removing the volume-restriction risk management measure.

There is no new toxicological, clinical or epidemiological evidence indicating the need to change the previous safety assessments. Therefore the conclusion of the previous safety assessment stands, that is, the consumption of phytosterol-enriched foods raises no safety concerns and a reference health standard is not warranted.

The previous risk assessments were based on national nutrition survey data (consumption data), and on the basis that consumers replaced all non-enriched products with enriched products. The volume of the package was not used to determine the dietary intake of phytosterols. Therefore, removing the package size restriction has no impact on previous dietary intake assessments.

Removing the volume restriction from phytosterol-enriched milk is likely to increase the consumption of such milk by target and non-target populations (mainly children). However, based on current usage data, provided by the Applicant, most consumers fall within the target-population, therefore any increased consumption by non-target consumers is likely to be low and there is no evidence to suggest this will have an adverse health effect. Any increased consumption occurring in the target population is likely to be of additional benefit as there is evidence, in the Application, that at least some of this population may not be receiving the minimum requirement as the current volume restriction has created a situation of inconvenience.

2. Introduction

2.1 The Applicant

Lion Dairy and Drinks (formerly National Foods) is a food and beverage provider in Australia and New Zealand.

2.2 The Application

Application A1065 – Packaging Size for Phytosterol-enriched Milk was made by National Foods (now Lion Dairy and Drinks) on 28 July 2011. It sought to remove the volume restriction on packages of milk containing phytosterols, phytostanols and their esters (phytosterol-enriched milk) in subclause 5(b) of Standard 2.5.1 – Milk, of the *Australia New Zealand Food Standards Code* (the Code).

Removal of the volume restriction aims to allow additional pack size options, potentially leading to more convenient and cost effective delivery of phytosterol-enriched milk to consumers.

2.3 The current Standard

Standard 2.5.1 – Milk, currently restricts the package size for phytosterol-enriched milk to one litre. Clause 2 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, requires certain labelling statements to be used for phytosterol-enriched milk.

The volume restriction was one of the risk management measures included in the approval of Application A434[2]. A volume restriction was included to discourage general household use because it was considered unlikely that everyone in a multiple person household would benefit from consumption of phytosterol-enriched milk. The volume restriction was recommended by FSANZ at the time of the initial assessment to help ameliorate concerns that arose because phytosterols were a relatively new addition to Australian and New Zealand diets.

The mandatory advisory statements advise that the product should be consumed as part of a healthy diet, may not be suitable for children under the age of five years and pregnant or lactating women and that plant sterols do not provide additional benefits when consumed in excess of three per day.

Before the then Australia and New Zealand Food Regulation Ministerial Council[3] approved the permission to allow the addition of phytosterols in milk, there were two reviews of FSANZ's original decision. The proposed volume restriction was not a matter considered in the reviews.

2.4 Reasons for accepting the Application

The Application was accepted for assessment on the basis that:

---

[2] http://www.foodstandards.gov.au/foodstandards/applications/applicationa434phytosterolestersinlowfatmilkandlowfatyoghurt/

[3] Now known as the COAG Legislative and Governance Forum on Food Regulation (the Forum)

- it complied with the procedural requirements under subsection 22(2)
- it related to a matter that warranted the variation of a food regulatory measure.

2.5 Procedure for assessment

The Application was assessed under the General Procedure.

2.6 Decision

The draft variation as proposed following assessment was approved without change. The draft variation on which submissions were sought is at Attachment A.

3. Summary of the findings

3.1 Risk assessment

The risk assessment for this Application is at Supporting Document 1 and includes the following key elements:

- assessment of any new information about the safety of phytosterols that has become available since the last FSANZ review in 2010

- assessment of consumer behaviour data provided as part of the Application

- assessment of the effectiveness of the risk management measures in Australia and New Zealand, Europe and the USA regarding phytosterol-enriched foods.

There was no new toxicological, clinical or epidemiological evidence indicating the need to change the previous safety assessments. Therefore the conclusion of the previous safety assessment remains, that is, the consumption of phytosterol enriched foods raises no safety concerns and a reference health standard is not warranted. This conclusion was supported by available information from Europe and the USA on the use of phytosterol-enriched foods.

For this Application, FSANZ considered it unnecessary to update previous dietary estimates. This Application does not introduce a new phytosterol-containing food or change the level of phytosterol equivalents. Previous risk assessments carried out by FSANZ estimated the dietary intake of phytosterols in Australia and New Zealand (FSANZ, 2002; FSANZ, 2004; FSANZ, 2002b) and reviewed the literature on purchasing behaviours and consumption patterns (FSANZ, 2009). Market share and product substitution issues were previously considered by FSANZ as part of the impact analysis in a number of assessment reports (FSANZ, 2009, 2010 a and b).

Food consumption data from 1995 and 2007 surveys were used in previous dietary intake estimates for phytosterol-enriched foods. The data from these surveys represent the most current, comprehensive, individual food consumption data for Australians available for use in modelling dietary exposure and intake. FSANZ considers that broad food consumption patterns are unlikely to have changed to such an extent that these surveys would not be suitable to use for this purpose.

Roy Morgan Single Source data from 2001 to 2008 indicates the frequency of total milk consumption in adults fluctuates somewhat but overall there were no dramatic changes. Generally, between 2001 and 2008 there was a downward trend in the proportion of young Australians consuming milk, while the proportion of older Australians consuming milk has trended upwards (Table 1). However, these data do not provide information about consumer behaviour regarding phytosterol products.

Table 1: 2001-2008 Frequency of total milk consumption - Australian adults by age groups

	14-17	18-29	30-49	50-69	70+
2001	85.3%	85.9%	80.9%	71.0%	61.8%
2002	84.6%	81.1%	78.6%	72.1%	66.1%
2003	84.1%	85.1%	83.1%	79.2%	73.4%
2004	80.1%	82.4%	82.4%	77.7%	70.9%
2005	77.1%	80.2%	80.5%	77.7%	70.7%
2006	74.4%	77.5%	80.2%	76.9%	72.6%
2007	72.7%	75.8%	79.2%	77.4%	71.3%
2008	75.7%	80.4%	82.3%	79.7%	73.7%

Sales data do not tell us how much of a food an individual consumes, or which members of a household consume it, nor how much of the food is wasted. Only National Nutrition Surveys provide the comprehensive, individual consumption data that FSANZ uses in dietary exposure assessments.

FSANZ believes that within the milk consumption sector, the proportion of consumers of no fat/low fat milks is likely to have increased recently but there is no quantitative data to assist in predicting intake of phytosterols. Any growth in consumption of low fat milks as a class of products is unlikely to be so great that it would negate estimates of phytosterol intake that are based on estimates of the amount of all types of milk that individuals consume.

Several assumptions and uncertainties associated with previous FSANZ risk assessments of phytosterols relate to the assessment of dietary intake (FSANZ 2010a, 2010b). These uncertainties are more likely to result in an overestimation of phytosterol intake in non-target populations. There is no new data relevant to the dietary intake of phytosterols that would reduce this uncertainty. Sales data would not have a major impact on uncertainty because it provides no clear information on long-term consumption of phytosterol milk nor can it be used to refine intake estimates for non-target groups.

Based on the maximum permitted phytosterols concentration and the nominated serve sizes of the food vehicles, the amount of phytosterols added to each food by the manufacturer is such that consumption of two-three serves of a single food or a mixture of different foods would provide enough phytosterols to achieve the cholesterol lowering effect.

FSANZ's 2010 analysis showed that in all population groups assessed, reduced fat milks were likely to contribute only 14–18% of total dietary intake of added phytosterols. Therefore, any change in the consumption of phytosterol-enriched low fat milk due to the removal of the volume restriction is likely to have a relatively small impact on total dietary intake of added phytosterols. Any increased consumption occurring in the target population is likely to be of additional benefit as there is evidence that at least some of this population may not be receiving the minimum effective amount of phytosterols required due to the current volume restriction.

Based on current usage data, indicating most consumers fall within the target-population, any increased consumption in non-target consumers was considered likely to be low and there was no evidence to suggest this would have an adverse health effect.

Although no further quantitative data on consumption of phytosterol enriched milk was provided in submissions, general comments on this topic were provided.

The comments received support our conclusion that any increased consumption in children resulting from the removal of the volume restriction is expected to be very low (see submissions from the New Zealand Food and Grocery Council and Raisio).

3.2 Risk management

3.2.1 Rationale for amending the current risk management measures

The current volume restriction was one of several risk management measures aimed at encouraging appropriate use by target consumers and discouraging use by non-target consumers in the same household. The other measures, which will remain, are mandatory advisory statements advising

- that the product should be consumed as part of a healthy diet
- may not be suitable for children under the age of five years and pregnant or lactating women, and that
- plant sterols do not provide additional benefits when consumed in excess of three per day),

and minimum and maximum amounts of total plant sterol equivalents phytosterol-enriched permitted in milk.

The risk assessment included consideration of the effectiveness of the current restriction on package size and what risk might arise to target and non-target consumers by removing it. As the volume restriction was part of a range of measures, it was difficult to assess its contribution, if any, to risk mitigation.

Market research information provided in the Application indicated most consumers of phytosterol-enriched milk in Australia were in the target population and children were generally absent from target consumer households. Purchasers of phytosterol-enriched milk in Australia (product currently not available in New Zealand) also purchase other milk types.

Raisio provided information from a 2006 (confidential) UK survey, which they stated showed similar consumer patterns to those mentioned above i.e. most consumption occurred in people aged 45 years or older, with no evidence that children under 5 years or women aged 17-44 years were heavy consumers.

Europe and the USA have a wider variety and longer history of use of phytosterol-enriched foods than Australia or New Zealand (the Raisio submission states cholesterol lowering plant stanol ester is now available in over 150 different products worldwide). Therefore, to help address the question of the risk management value of the volume restriction in milk, FSANZ reviewed the risk management measures in these international areas as well as the history of reported adverse events from the consumption of phytosterol-enriched foods.

FSANZ considers the information from Europe and the USA (where there are no volume restrictions on phytosterol-enriched milk) indicates that the lack of a volume restriction does not lead to adverse health effects from consumption of phytosterol-enriched foods. This finding is supported by company information held by Raisio.

3.2.2 Summary of submissions

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions.

Every submission on an application or proposal is reviewed by FSANZ staff, who examine the issues identified and prepare a response to those issues. While not all comments can be taken on board during the process, they are valued and all contribute to the rigour of our assessment.

FSANZ called for public comment from 26 March to 7 May 2012.

Comments were specifically requested on the scientific aspects of the Application including safety considerations, as well as information relating to consumption in target and non-target consumers and any potential costs or benefits associated with the proposed removal of the volume restriction for milk. As this Application was assessed under a General Procedure, there was only one round of public comment.

Ten submissions were received during the public consultation period. Six submitters supported the Application (one government agency, three professional organisations and one dairy product producer and one ingredient manufacturer). Three government agencies and one non-governmental organisation raised concerns about the assessment presented in the Call for Submissions report. FSANZ provided further clarification to agencies that raised questions about the applicability of the Ministerial Council Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals. Following this clarification, two of the agencies supported progressing the Application.

FSANZ thanks all submitters for their comments, and has taken these comments into account in preparing the Approval report for this Application. A summary of these and FSANZ's response is provided in **Table 1.**

Table 1: Summary of issues raised in submissions

Issue	Raised by	FSANZ Response
Applicability of the Ministerial Council Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals.	Department of Health & Human Services, Tasmania Environmental Health Unit, Queensland Health Victorian Health Department	Assessing cumulative effects of phytosterols in multiple food products is important. Details of the FSANZ response are in sections 3.1, "Risk Assessment" and 4.2.4, "*any written Ministerial policy guidelines*" of this report.
Evidence that larger packaging sizes will result in cheaper price per unit volume.	Heart Foundation	The Applicant has stated that the 3 L milk will cost less than the equivalent 3x 1 L milk. It is reasonable to assume that larger volume containers are going to be cheaper per unit volume than multiple smaller volume containers. Consumers can maximise their utility by selecting the pack size that best meets their needs.
Research requested to show that price is prohibitive for target consumers in low income groups, as opposed to other barriers (e.g. education, self-efficacy).	Heart Foundation	In general, price is a significant determinant of purchase behaviour. To the extent that price is limiting lower income people purchasing then the proposed changes may assist. FSANZ acknowledges that other factors also influence purchase.

Issue	Raised by	FSANZ Response
Concern that there is insufficient information on the health effects, especially in the long-term and for pregnant women, unborn children, infants and children.	Environmental Health Unit, Queensland Health Heart Foundation Victorian Health Department	This issue is addressed in SD1, section 3.2, answer to Question 2a). The risk assessments conducted by FSANZ have taken into account long-term exposure. Consideration of all available information, including animal toxicity data and epidemiological data raised no safety concerns.
Strengthen the requirements for legibility and placement of the mandatory advisory statement and declarations	Queensland Health	Additional conditions for the presentation of advisory statements (e.g. prescribed font size, format and placement) have not been considered under this Application. The advisory statements apply to all foods containing added phytosterols, phytostanols or their esters. Hence applying additional conditions to all these foods is beyond the scope of this Application and it would be inconsistent to apply increased prescription for advisory statements just to milk containing added phytosterols.
Assumption that phytosterol-enriched margarines are appropriate comparators to phytosterol-enriched milk for consideration of package size	Victorian Health Department	The rationale for FSANZ accepting this comparison can be found in section 4.2.4 of this report.

3.3 Risk communication

FSANZ applied a basic communication strategy to this Application. The call for submissions was notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and the *Food Standards News*.

Subscribers and interested parties were also notified about the availability of reports for public comment.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options. The issues raised in the public submission were evaluated and addressed in this Report.

Documents relating to A1065 are available on the website at http://www.foodstandards.gov.au/foodstandards/applications/applicationa1065pack5285.cfm

The draft variation was considered for approval by the FSANZ Board taking into account public comments received from the call for submissions.

The Applicant and individuals and organisations that made submissions on this Application, will be notified at each stage of the assessment.

The FSANZ Board decision has been notified to the Forum. If the decision is not subject to a

request for a review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

4. Reasons for decision

The draft variation to Standard 2.5.1, as proposed following assessment, was approved without change on the basis of the available evidence and for the following reasons:

- no public health or safety issues have been identified arising from consumption of phytosterols
- the market research information provided in the Application indicates consumers may be disadvantaged by a restricted range of package sizes
- consistency with the risk management approach in the EU and USA
- the availability of other risk management measures.

FSANZ considers it is appropriate to retain the other risk management measures of mandatory advisory statements as these assist in encouraging appropriate use.

4.1 Section 29

FSANZ had regard to the following matters under section 29 of the FSANZ Act:

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweighed the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure
- whether other measures (available to FSANZ or not) would be more cost-effective than a food regulatory measure varied as a result of the Application
- any relevant New Zealand standards
- any other relevant matters.

FSANZ concluded that:

- Based on the results of the qualitative cost benefit analysis below, removing the volume restriction would not impose significant costs for government agencies, consumers or manufacturers.
- There are no other measures than a variation to Standard 2.5.1 that could achieve the same end.
- There are no relevant New Zealand standards that would impact on our decision to amend the Code.

4.1.1 Cost Benefit Analysis

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 6 October 2011 (reference 13135), confirmed that a Regulation Impact Statement (RIS) was not required for this Application. The proposed variation to the Code is considered minor and machinery in nature. However, FSANZ performed a qualitative assessment of the costs and benefits for the two regulatory options.

Option 1: Approve the draft variation

Sector	Costs or benefits to sector
Consumers	Removing the volume restriction is expected to benefit the target consumers by: • enabling a broader availability of phytosterol-enriched milk as many retailers give preference to larger size packages due to limitations on available shelf space • potentially enabling phytosterol-enriched milk to be more affordable (bigger packs of the same product may provide lower unit cost to the purchaser). Submissions from AFGC and Raisio Nutrition Ltd supported the logic behind this potential benefit. • enabling more efficient storage in the household. The proposed variation to the Code could disadvantage the non-target-consumer from mixed consumer households by: • increasing their consumption because more phytosterol-enriched milk is available in the household than previously. This disadvantage would be an economic one rather than a health one as no adverse public health of safety issues have been identified from consumption of phytosterols.
Industry	The proposed draft variation could advantage industry by: • potentially increasing market volumes by enabling phytosterol-enriched milk to be supplied to outlets where 1 litre containers are not currently sold • allowing for increased production efficiency by supplying larger packs.
Government	A minor benefit for the Government is expected as there would be no requirement for any compliance monitoring of package size.

Option 1: Reject the draft variation

Sector	Costs or benefits to sector
Consumers	There are no benefits to target-consumers from this Option. Rejecting the Application has potential to reduce the availability of the product in retail outlets as we have been advised that it is already losing out to more economically attractive chiller cabinet products.
Industry	No change for milk suppliers.
Government	No change

4.2 Addressing FSANZ's objectives for standards setting

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Application as follows.

4.2.1 Protection of public health and safety

The consumption of phytosterol-enriched milk raises no public health or safety concerns.

4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

Current mandatory advisory statements, which will remain, assist consumers in appropriate use of phytosterol-enriched milks.

4.2.3 The prevention of misleading or deceptive conduct

No issues were identified.

4.2.4 Subsection 18(2) considerations

FSANZ has also had regard to the objectives set out in subsection 18(2):

- *the need for standards to be based on risk analysis using the best available scientific evidence*

  FSANZ has previously assessed and characterised the risk from consumption of foods containing added phytosterols, phytostanols and their fatty acid esters. Collectively, these risk assessments have considered all available information (national and international), including animal toxicity data and epidemiological data, relevant to the safety of phytosterols, phytostanols and their fatty acid esters.

  FSANZ conducted a search of the scientific literature published since previous assessments and concluded that there were no new publications indicating a potential for safety concerns in any population group consuming foods enriched with phytosterols, phytostanols and their fatty acid esters.

- *the promotion of consistency between domestic and international food standards*

  The requirements in the EU and USA for package size for phytosterol-enriched milk have been taken into consideration. Package size restrictions do not apply in the above mentioned countries/jurisdictions.

- *the desirability of an efficient and internationally competitive food industry*

  There is no significant international trade in fresh liquid milks and the removal or retention of the current volume restriction is unlikely to have a significant impact on international trade.

- *the promotion of fair trading in food*

  The Application questions the consistency, logic and fairness in the differences in volume restriction for the foods that are currently allowed to contain phytosterols. In particular, it challenges the fairness between the absence of a volume restriction for “edible oil spreads” enriched with phytosterols, compared with milk. Both milk and edible spreads are often consumed throughout the day i.e. have similar patterns of use, however a typical size tub of spread (250 g) can contain around 25 individual serves (approximately eight days’ worth of recommended daily amounts) compared with a 1 L package of milk which contains four serves (a maximum of two days of recommended daily amounts). Removing the package size restriction eliminates this impediment.

  In its submission, Victoria challenged whether edible oils spreads (referred to in the submission as margarine) were trade comparators to milk.

  The basis of the challenge was that these two products varied with respect to shelf-life

and consumption patterns. FSANZ acknowledges these differences but because they are both staple foods for the general population, are usually consumed daily throughout the day and both have permission to contain phytosterols, we have accepted them as trade comparators.

- *any written policy guidelines formulated by the Forum (formerly the Ministerial Council)*

  Several government submissions considered that removing the volume restriction is a new permission for phytosterols and as such the Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals did apply. This is contrary to FSANZ's statement in its assessment summary on which public comment was called.

  FSANZ's rationale for indicating the above mentioned policy guideline does not apply was that the Application did not add a new phytosterol or alter the level of sterol equivalents per unit volume.

  The fundamental concern of the government agencies which raised concern in this area was the assessment of cumulative impact. FSANZ agrees that assessing cumulative effects of phytosterols in multiple food products is important. However, because this has been addressed in previous applications for phytosterols and the scope of A1065 did not affect previous dietary exposure estimates, cumulative intake was not reassessed as part of the consideration of this Application (see section 3.1, Risk Assessment for further details).

4.3 Implementation

The variation will come into effect on gazettal.

5. References

FSANZ (2002) Application 417 - Tall oil non-esterified phytosterols as novel food ingredients: FSANZ: Canberra.

FSANZ (2004) Final Assessment Report: Application A433 - Phytosterol esters derived from vegetable oils in breakfast cereals.

FSANZ (2009) Assessment Report, Application 1019 - Exclusive use of phytosterol esters in low- fat cheese.

FSANZ (2010a) Approval Report: Application A1019 - Exclusive use of phytosterol esters in low-fat cheese.

FSANZ (2010b) Approval Report: Application A1024 - Equivalence of plant stanols, sterols & their fatty acid esters.

Attachments

A. Approved variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement

Attachment A – Approved variation to the *Australia New Zealand Food Standards Code*

Food Standards (Application A1065 – Packaging size for Phytosterol-enriched Milk) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated TO BE COMPLETED

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards* (*Application A1065 – Packaging size for Phytosterol-enriched Milk) Variation.*

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standard 2.5.1 in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on **the date of gazettal**.

SCHEDULE

[1] ***Standard 2.5.1*** *is varied by deleting* paragraph 5(b*)*.

Attachment B – Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1065 which seeks to remove the current volume restriction on package size for milk enriched with phytosterols. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation to Standard 2.5.1.

Following consideration by the COAG Legislative and Governance Forum on Food Regulation[4], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislative Instruments Act 2003*.

2. Purpose and operation

The Authority has prepared a draft variation of Standard 2.5.1 to delete paragraph 5(b), which refers to the package size for milk being restricted to 1 L.

The variation will remove the restriction on package size for phytosterol enriched milk so that phytosterol-enriched milk can be sold in any volume, consistent with other forms of liquid milk packaging.

The volume restriction was one of several risk management measures designed to encourage appropriate use and consumption of phytosterol-enriched milk by target consumers and discourage use by non-target consumers. Other remaining risk management measures, including mandatory advisory label requirements, are considered by FSANZ to be sufficient for achieving those aims.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

[4] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1065 has included one round of public consultation. Submissions were called for on 26 March 2012 for a six-week consultation period.

A Regulation Impact Statement (RIS) was not required because the proposed variation to Standard 2.5.1 is likely to only have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

The variation omits paragraph 5(b) of Standard 2.5.1 and thereby, removes the restriction on package size for phytosterol enriched milk, which enables phytosterol-enriched milk to be sold in any volume.